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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,612	01/05/2004	T. Erik Mirkov	017575.0774 (TAMUS 1910)	2393
5073	7590	01/12/2006	EXAMINER	
BAKER BOTTS L.L.P. 2001 ROSS AVENUE SUITE 600 DALLAS, TX 75201-2980			MCELWAIN, ELIZABETH F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/751,612

Applicant(s)

MIRKOV ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 is/are allowed.
- 6) ☒ Claim(s) 2-14 and 16-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/3/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed September 9, 2005 has been entered.

Claim 15 has been cancelled.

Claim 34 is newly submitted.

Claims 2-5, 7, 11, 13, 16 and 17 are currently amended.

Claims 2-14 and 16-34 are pending and are examined on the merits.

The objections to the specification and the drawings have been withdrawn.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. Claims 2-14 and 16-34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the last office action for claims 2-33.
3. Applicants' arguments filed September 9, 2005 have been fully considered but they are not persuasive. Applicants assert that through SEQ ID NO: 1 at least a partial structure and a functional characteristic is provided for the genus claimed. The Examiner maintains that only one sequence has been provided in the form of SEQ ID NO: 1, which has been shown to exhibit the functional activity of having stem-regulated promoter activity, while the claim is drawn to a whole genus of sequences that may have as little as 60% identity to SEQ ID NO: 1. The

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specification does not teach what portions of SEQ ID NO: 1 would have to be retained for a nucleic acid sequence to have stem-regulated promoter activity.

4. Claims 2-14 and 16-34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the promoter having stem-regulated activity of SEQ ID NO: 1, does not reasonably provide enablement for any nucleic acid that is at least 60% identical to SEQ ID NO: 1 having stem regulated activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 1-33.

5. Applicants' arguments filed September 9, 2005 have been fully considered but they are not persuasive. Applicants assert that because the level of skill in the art is high, with most practitioners being at least Ph.D. candidates or scientists already holding a Ph.D., that the level of direction required by one skilled in the art is low. Applicant further states that the specification provides examples and detailed descriptions of how to test promoters to determine stem-regulated or defense-induced activity, and that experimentation is not undue if a reasonable amount of guidance is provided, even if it is trial and error.

6. The Examiner maintains that applicants have provided one example in the form of SEQ ID NO: 1, which is 3016 nucleotides long and has stem-regulated promoter activity. However, applicants are claiming any sequence that is at least 60% identical to SEQ ID NO: 1. Therefore, up to 40% of the nucleotides may be substituted for, hence any of 1 to 1206 nucleotides may be varied. With 3^{3016} possible single nucleotide substitutions at any of 1 to 1206 nucleotide

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positions, this is an enormous number of possible sequences to be tested without any guidance with regard to which nucleotides may be substituted for, while retaining the stem-regulated promoter activity. While a person of skill in the art would know how to test for stem-regulated activity, it would require undue experimentation to identify other sequences having the claimed activity, in view of the unpredictability with regard to required sequence regions in promoters, as stated in the last office action, and given the enormous breadth of the claims, and in view of the level of ordinary skill in the art, which is high.

The rejections of the claims under 35 USC 112, 2nd paragraph are withdrawn in view of the amendment of the claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM